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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,671	01/10/2002	Katrina L. Mealey	4630-61733	9719

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EXAMINER

SAKELARIS, SALLY A

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 09/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/044,671	MEALEY ET AL.	
	Examiner	Art Unit	
	Sally A Sakelarlis	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-42 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 2-3, 4-5, and 6-13 are drawn to a method of detecting ivermectin sensitivity in a subject, comprising determining whether a gene truncation mutation in a *mdr1*-encoding sequence using nucleic acids, probes, primers, and a nucleotide array as classified in for example, Class 435, subclasses 69.1, 252.3, 287.2, and 320.1, Class 536, subclass 23.5, 24.31, 24.33, 23.1, 24.33, and 24.3.

II. Claims 1, 2, 4-5, 14-15, and 17-19 are drawn to a method of detecting ivermectin sensitivity in a subject, comprising determining whether a truncated P-gp is present in the subject using protein detection methods as classified in for example, Class 435, subclass 7.1, Class 514, subclass 12 and Class 530, subclasses 300 and 350.

III. Claims 1, 2, 4-5, and 14-19 are drawn to a method of detecting ivermectin sensitivity in a subject, comprising determining whether a truncated P-gp is present in the subject wherein the binding agent is an antibody as classified in for example, Class 514, subclass 2.

IV. Claims 20, 21, 29-36, 39-42 are drawn to a method of making a treatment decision comprising determining a P-gp influenced biological affect of a drug or a compound on a canine cellular system as classified for example in Class 514, subclass 44.

V. Claims 22-23, 27, and 28 are drawn to kits containing nucleic acids and oligonucleotides that hybridize to the canine *mdr-1* gene truncation mutation as classified in for example, Class 435, subclass 6.

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VI. Claims 22, 24 and 26 are drawn to kits containing a protein binding agent as classified in for example, Class 530 subclass 350.

VII. Claims 22, 24-26 are drawn to kits containing an antibody as the binding agent as classified in for example, Class 530 subclass 387.

VIII. Claims 37 and 38 are drawn to an animal model useful for studying a P-gp influenced biological effect of a compound as classified in for example, Class 800, subclass 8.

2. The inventions are distinct, each from the other because of the following reasons:

a. The methods of inventions I- IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially distinct methods using structurally and functionally different biomolecules (ie Nucleotides, proteins, and antibodies) which require the use of different reagents, have different process steps and have distinct objectives. The method of invention I includes steps involving the detection of a nucleotide. Invention II includes a method for detecting the presence of a protein. The method of invention III involves the necessary steps for identifying a truncated protein through the use of an antibody, binding agent. Lastly, the method of group IV includes steps involved with making a treatment decision comprising determining the biological affect of a drug or compound. In the instant case the different aforementioned inventions all have different functions and are not disclosed as capable of use together.

b. Inventions V and VI are patentably distinct in structure and physiochemical properties. Invention V is drawn to nucleic acids whereas invention VI is drawn to proteins. Because nucleic acids are composed of nucleotides and proteins are composed of amino acids, the inventions have different structural and functional properties. Furthermore, the compositions are utilized in different methodologies, such that nucleic acids may be utilized in hybridization assays, while the proteins may be utilized in ligand binding assays or to generate antibodies. The proteins of invention VI does not require the particular products of the nucleic acids of group V since the proteins of invention VI can be isolated from natural sources or chemically synthesized.

c. Inventions V and VII are patentably distinct in structure and physiochemical properties. Invention V is drawn to nucleic acids whereas invention VII is drawn to antibodies. Because nucleic acids are composed of nucleotides and antibodies are composed of amino acids, the inventions have different structural and functional properties. Furthermore, the compositions are utilized in different methodologies, such that nucleic acids may be utilized in hybridization assays, while the antibodies may be utilized in assays to detect the presence or absence of a protein. The nucleic acids of invention V are not required to obtain the antibodies of invention VII.

d. Inventions VI and VII are patentably distinct in structure and physiochemical properties. Invention VI is drawn to polypeptides whereas invention VII is drawn to antibodies. The polypeptide of Group VI is composed of amino acids linked in peptide bonds and arranged spatially in a number of different tertiary structures including alpha helices, beta-pleated sheets, and hydrophobic loops (transmembrane domain). The antibody of Group VII is also composed of amino acids linked in peptide bonds and arranged spatially in a very specific tertiary structure

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that allows that antibody to specifically bind to particular regions, i.e. epitopes, of the encoded polypeptide. Further, antibodies are glycosylated and their tertiary structure is unique, where four subunits (2 light chains and 2 heavy chains) associated via disulfide bonds into a Y-shaped symmetric dimer. The products of inventions VI and VII are utilized in materially different processes such that the proteins of invention VI may be used to make a fusion protein while the antibodies of invention VII may be used in an immunoassay. Consequently, the reagents, reaction conditions, and reaction parameters required to make or use each invention are different. Therefore, the inventions of Groups VI, and VII are patentably distinct from each other.

e. Inventions V and VIII, VI and VIII, VII and VIII are patentably distinct in structure and physiochemical properties. Each of groups V, VI, and VII are drawn to a distinct biomolecule, while the invention of Group VIII is drawn to a transgenic animal, an animal model comprising a Collie. The products of inventions V-VII and VIII are utilized in materially different processes such that the biomolecules of groups V-VII can be used in various research methods while the Collie of Group VIII can be used as a household pet wherein it may be used to play fetch or alternatively accompany its master on walks or runs. Consequently, the reagents, reaction conditions, and reaction parameters required to make or use each invention are different. Therefore, the inventions of Groups V and VIII, VI and VIII, VII and VIII are patentably distinct from each other.

f. Inventions I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP

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§ 806.05(h)). In the instant case the nucleic acids of invention V can be used in a materially different processes such as for sequencing reagents and involving amplification and sequencing methods in order to achieve the objective of genotyping an individual for pedigree analysis.

g. Inventions I and VI, VII, and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions and are not disclosed as capable of use together because the methods involving nucleic acids of invention I do not require the polypeptides, antibodies and animal models of inventions VI, VII, and VIII.

h. Inventions II and VI are related as products and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides of invention VI can be used in a materially different process such as for determining the protein's folding conformation and the resulting crystal structure or for generating antibodies.

i. Inventions II and V, VII, VIII, are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions and are not disclosed as capable of use together because the polypeptides of invention VI are not required to practice the methods of inventions V, VII and VIII involving nucleotides, antibodies and an animal model respectively.

j. Inventions III and VII are related as products and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method of invention III can be used in a materially different process such as for finding a binding agent that is not an antibody.

k. Inventions III and V, VI, and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions and are not disclosed as capable of use together because the method involving antibodies of invention III, does not require the nucleotides, polypeptides, or animal model of inventions V, VI, and VIII respectively.

l. Inventions IV and VIII are related as products and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of invention VIII can be used in a materially different process such as for a guide dog that provides walking guidance for a blind owner.

m. Inventions IV and V, VI, and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions and are not disclosed as capable of

use together because the method involving making a treatment decision of invention IV, does not require the nucleotides, polypeptides, or antibodies of inventions V, VI, and VII respectively.

3. Applicant is advised that examination will be restricted to only the elected group and single biomolecule within each group(ie, nucleic acid, protein, or antibody) and should not be construed as a species election.

Claims 1, 2, 4, and 5 link the inventions of Groups I-III, claims 14, 15, and 17-19 link the inventions of groups II and III, claim 22 links the inventions of groups V-VII, and claims 24 and 26 link the inventions of groups VI and VII. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), as stated above. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

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4. Because these invention are distinct for the reasons given above and have acquired a different status in the art as demonstrated by their different classification and recognized divergent subject matter and because inventions I-X require different searches that are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

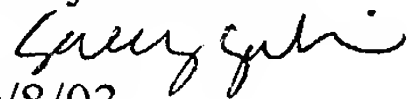
5. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

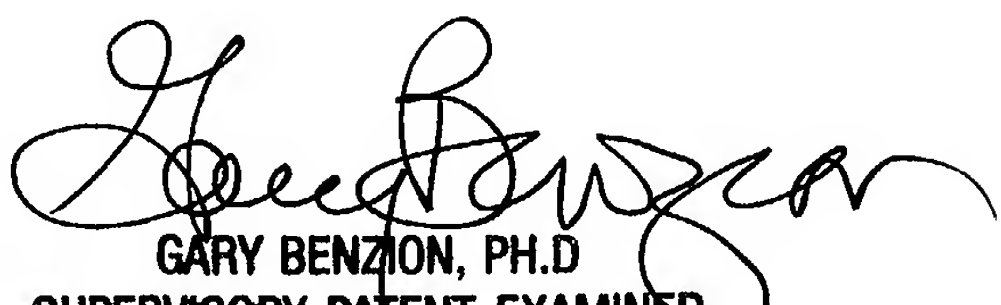
Any inquiry concerning this communication or earlier communication from the examiner should be directed to Sally Sakelaris whose telephone number is (703) 306-0284. The examiner can normally be reached on Monday-Friday from 8:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W.Gary Jones, can be reached on (703)308-1152. The fax number for the Technology Center is (703)305-3014 or (703)305-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to Chantai Dessau whose telephone number is (703)605-1237.

Sally Sakelaris


9/8/03


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